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Dated: September 1, 2005 Signature: (Lynn L. Januelis, Ph.D.)

Docket No.: 01017/35966B (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Han et al.

Application No.: 10/758,672 Group Art Unit: 1652

Filed: January 15, 2004 Examiner: E. Slobodyansky

For: The Human E3α Ubiquitin Ligase Family

RESPONSE TO OFFICE ACTION MAILED AUGUST 1, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the restriction requirement imposed in the Office Action mailed August 1, 2005 (the "Office Action"), the applicants hereby elect Group IV (drawn to a polypeptide of SEQ ID NO: 2, compositions and fusion proteins comprising thereof), with traverse, for prosecution on the merits at this time. This election is timely filed.

As an initial matter, the applicants request clarification of the nature and basis for imposing a restriction requirement among several of the claim groups identified by the examiner. For example, at page 3 of the Office Action, the examiner asserted that "[t]he inventions are distinct, each from the other because of the following reasons: A polypeptide of Group IV and a DNA used in methods of Groups I and III are divergent molecules having different structures, functions and utilities." A proper claim restriction requires that the claims either be drawn to independent subject matters or, if dependent subject matters, that the claims be drawn to distinct subject matters. *See* M.P.E.P. § 802.01. Independent subject matters, of course, are distinct subject matters. Therefore, the examiner's assertion that the inventions are distinct does not identify the basis for imposing a restriction requirement in that it does not reveal whether the examiner is asserting that the inventions are independent or dependent but distinct. In this response, the applicants interpret the examiner's assertion as identifying the subject matters of claim Groups I, III, and IV as dependent yet distinct subject matters, and not as independent subject matters. Additionally, the above quote from the Office Action asserts that the molecules are divergent and have different structures, functions and utilities. The applicants request

clarification of the meaning of "divergent" molecules, and further request the provision in the M.P.E.P. that provides a basis for restricting assertedly distinct inventions on the basis of different structures, functions and utilities.

In addition to asserting that the subject matters of claim Groups I, III, and IV, were drawn to divergent molecules having different structures, functions and utilities, the examiner asserted that "the nucleic acid molecule use in inventions I and III can be used for the production of huE3α polypeptide of Group I as well as a hybridization probe in a method of Group III." Office Action at page 3. The applicants submit that the use of any nucleic acid molecule in the methods of claim Groups I and III is irrelevant to a determination of the propriety of restricting those claim Groups. As noted by the examiner in defining the claim groups, the claim of Group I, claim 9, is drawn to "a method of producing a huE3 α polypeptide using a cell transformed with a DNA encoding SE ID NO:2 . . . ." Office Action at page 2. Analogously, the examiner characterized the claim of Group III, claim 12, as being drawn to "a method for determining whether a compound inhibits a huE3 α polypeptide production . . . ." *Id.* The examiner defined the subject matter of claim Group IV (*see, e.g.*, claim 13) as being "drawn to a polypeptide of SEQ ID NO:2, a composition and a fusion protein comprising thereof . . . ." Office Action at page 3. Thus, using the examiner's own characterizations of the subject matters of claim Groups I, III, and IV, the issue is whether it is proper to restrict between the Group I claim drawn to a method of producing, or making, a huE3α polypeptide and the Group IV claims drawn to isolated huE3 α polypeptides. It is irrelevant that the Group I claim (claim 9) recites the use of a nucleic acid molecule to produce the polypeptide within a host cell. The focus of the inquiry into distinctness remains the process, or method, for producing or making the polypeptide. Thus, the issue is whether claim Groups I and IV are drawn to distinct methods of making and products made. M.P.E.P. § 806.05(f) is controlling under these circumstances. That section of the M.P.E.P. provides that "[a] process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown: (A) that the process *as claimed* is not an obvious process of making the product and the process as *claimed* can be used to make other and fiferent products; or (B) that the product *as claimed* can be made by another and materially different process." The examiner did not cite § 806.05(f) and did not establish the process of claim Group I was not an obvious process of making the polypeptide, did not establish that the process of claim Group I could be used to make other and different products and did not establish that the product polypeptide could be made by another and materially different process.

Accordingly, the examiner has failed to establish a *prima facie* basis for restricting the claims of Groups I and IV and the restriction should be withdrawn.

The restriction between claim Groups III and IV is also unsupported. Claim Group IV is drawn to isolated polypeptides. Claim Group III is drawn to methods of using the polypeptides to determine whether a compound inhibits production of the polypeptides. Thus, the proper relationship between these claim groups is a product and a method of using the product. Again, the examiner's focus was misplaced in identifying a nucleic acid molecule (claim language) or DNA (examiner's language) used in the methods. Use of a nucleic acid molecule in a method of producing the polypeptide is irrelevant; for purposes of imposing a restriction requirement, the focus must remain on the fact that the claimed processes are methods of producing the polypeptides. M.P.E.P. § 806.05(h) provides controlling guidance in considering restriction practice between claims drawn to a product and a method of using that product. That provision states that "[a] product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process. The burden is on the examiner to provide an example . . . ." The support offered by the examiner related to use of the nucleic acid molecule to produce the polypeptide or for use as a hybridization probe. Office Action at page 3. Whether the nucleic acid molecule recited in the product claims, e.g., claim 13, can be used in processes other than the process of claim Group III is irrelevant to providing a proper basis for imposing a restriction requirement. The issue, as defined in M.P.E.P. § 806.05(h), is whether the process of using the product, not some other compound, can be shown to be an invention distinct from the product itself. The examiner has not addressed whether the process of determining whether a compound is an inhibitor (method of the Group III claim) can be practiced with a product that materially differed from the polypeptide (product of Group IV claims), and has not shown that the polypeptide product (not the nucleic acid molecule) can be used in a materially different process from that process recited in claim Group III. Further, the examiner has not provided an example relating to the polypeptide product or the process of using that product. For all of these reasons, the applicants submit that the examiner has not established a *prima facie* basis for restricting claim Group III and IV and the restriction should be withdrawn.

Support for restricting among claim Group II (claim 12, drawn to a method for determining polypeptide inhibitors), Group V (claim 58, drawn to a method of identifying a compound that binds to the polypeptide) and Group IV(e.g., claim 13, drawn to the isolated

polypeptides) was provided by citing to M.P.E.P. § 806.05(h) and asserting that the claimed subject matters were related as product and processes of use. In support, the examiner asserted that the product polypeptide could be used in materially different processes, i.e., "a polypeptide of SEQ ID NO:2 can be used in a method of Group II as a huE3α polypeptide, in a method of Group V and for the production of an antibody, for example." Office Action at pages 3-4. The methods of Groups II and V, however, are the products of the examiner's own grouping of claims. It is a mere tautology for the examiner to assert that claims belong to different claim groups and offer as justification for the separate groupings the fact that the claims are found in different groups. This point is made because the above-quoted statement from the Office Action is the sole support for imposing a restriction requirement among the claims of Groups II, IV, and V. Moreover, the identification of a method for the production of an antibody does not establish that the polypeptide product can be used in materially different processes. An antibody would be recognized as a molecule capable of binding the polypeptide and an antibody to a polypeptide would be widely recognized as frequently inhibiting an activity of the polypeptide when bound. Further, one of skill would recognize that part of a method for producing an anti-polypeptide antibody involves exposure of the antigenic polypeptide to the elicited antibodies to find or identify the appropriate binding molecule. The examiner has not shown how a method for producing an antibody that involved contact between the polypeptide and potential antibody would materially differ from the Group II method for determining whether a compound (e.g., an antibody) inhibits polypeptide activity. Analogously, the examiner has not shown how the above-described method for producing an antibody would materially differ from the Group V method of identifying a binding compound. Thus, the mere recitation of methods of claim Groups II, V and a method for producing an antibody does not establish that the polypeptide product of claim Group IV can be used in a process that materially differs from either the method of claim Group II or the method of claim Group V. Accordingly, the examiner has not established a *prima facie* basis for restricting these claim groups and the restriction should be withdrawn.

The examiner also provided remarks in support of the restriction among the methods of claim Groups I-IV, maintaining that the methods "are patentably distinct because they employ patentably distinct compounds such as a polypeptide and a polynucleotide and/or have different protocols, comprise different steps, use different compounds, are carried out under different conditions and have different utilities. The applicants have noted that the "distinct" or "different" compounds in the form of polypeptides and their encoding nucleic acid molecules are

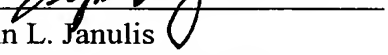
irrelevant to restriction practice relating to the present application. The polypeptides, and methods of making or using those polypeptides, are the subject matter of the claims. Beyond that observation, the applicants note that the examiner has not cited any basis in the M.P.E.P. for the four-way restriction requirement. The applicants find no provision in the M.P.E.P. that provides a basis for restricting claims as patentably distinct merely because they recite protocols that differ in some unspecified way, or that recite steps that differ in some undefined way. Further, the examiner globally asserted that the methods of Groups I, II, III and V differ in "being carried out under different conditions." Office Action at page 4. The applicants request specific identification of the different conditions. While claim 9 of Group I recites that the culturing of step c) be carried out under conditions suitable to express the polypeptide, the applicants cannot identify any claim of Groups II, III or V that recite different conditions. In fact, the claim of Groups II and III, i.e., claim 12, recites that the polypeptide is expressed in the host cell defined according to claim 9, which means that the conditions of claim Groups II and III must at least include the conditions of claim Group I. The single claim of Group V, claim 58, does not recite any condition. Thus, the applicants request that the examiner identify the different conditions. Finally, the applicants point out that claim Groups II and III contain the same, single claim, i.e., claim 12. It is logically impossible for the same claim to recite different compounds, different protocols, different steps, different conditions or different utilities. Based on the failure to cite any authority to support the restriction between any two of the four groups of method claims, i.e., Groups I, II, III and V, and based upon the failure to establish that the methods are patentably distinct because they are capable of separate manufacture, use or sale and are patentable over each other (*see* M.P.E.P. § 803.02), the applicants submit that the examiner has failed to establish a *prima facie* basis for imposing a restriction requirement between any of two of the method groups of claims, i.e., claim Groups I, II, III and V, and the restriction requirement should be withdrawn.

CONCLUSION

For the foregoing reasons, the applicants request reconsideration and withdrawal of the restriction requirement. Should the examiner have any questions or comments regarding this response or the application, the examiner is invited to contact the undersigned at the number indicated.

Dated: September 1, 2005

Respectfully submitted,

By 

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